

3

prosthetic heart valve in a patient's heart chamber. At least one non-looped wire and looped wire pair is operatively connected with an expanded prosthetic heart valve frame that is collapsed within a delivery catheter lumen having its distal end positioned in the subject heart chamber. The collapsed prosthetic heart valve frame is translated through the delivery catheter lumen to and out of its distal end where the prosthetic heart valve expands to a working configuration. The wire(s) of the non-looped and looped wire pair may be manipulated by pulling proximally or pushing distally to position or reposition the expanded prosthetic stent into position, then released from connection with the positioned stent and withdrawn from the patient.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. 1 illustrates a perspective view of a distal end of one embodiment of the present invention;

FIG. 2 illustrates a perspective view of one embodiment of the present invention; and

FIG. 3 illustrates a side, cutaway view of a proximal end of one embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Various embodiments of the present invention are disclosed in the Figures for providing percutaneous access to the valve of interest via one of at least the following known access routes: transapical; transfemoral; transatrial; and transseptal delivery techniques. Each of these access routes may be used for the embodiments disclosed herein.

FIG. 1 illustrates the distal end of an exemplary embodiment of system 100 comprising a set of positioning/release wire and loop pairs that are translatable and rotatable within the lumen of a delivery catheter or sheath, and extending distally outwardly away from the distal end of the delivery catheter or sheath 102 and the lumen 104 defined there-through. Each pair consists of a looped wire L and a non-looped wire W. As shown, three pairs of non-looped wires W and looped L wires are provided, though the skilled artisan will recognize that as few as one pair and more than three pairs of wires may be employed. Each non-looped wire W may be threaded around or otherwise operatively connected with one or more struts of an exemplary stent and further threaded through a loop formed at the distal end of the looped wire L to form the non-looped and looped wire pair, preferably at a junction between two struts forming a portion of a stent cell, and as will be discussed further below.

It is advantageous from positioning and repositioning perspectives, once the stent has been delivered and expanded within a heart chamber, to provide the non-looped wire W and looped wire L pair connections at spaced-apart locations on the stent frame to optimize the operator's ability to change the position of the expanding or expanded frame. Thus, a first wire pair may be provided on one side of the stent frame a second wire pair may be provided on the other side of the stent frame. In this system, it is now possible for the operator to manipulate the position of the expanded stent frame by pulling proximally and/or pushing distally on one or more of the wires and/or loops and/or wire and loop pairs. A third wire pair may be provided at another location spaced apart from the first and second wire pairs to further enhance repositioning and manipulation capabilities, e.g., near the upper portion of the expanded stent. These connection locations are merely exemplary, the skilled artisan will

4

recognize that a plurality of such locations are possible, each of which are within the scope of the present invention.

FIG. 2 illustrates one such non-looped wire W and looped wire L pair P comprising an interconnected non-looped wire W and looped wire L and connection with an expandable and collapsible prosthetic mitral valve 200 defined by a stent frame 201 formed by interconnecting struts 202 that form or define cells C, wherein the cells C are formed by junction points J where two struts 202 are operatively engaged or interconnected as shown. In the exemplary prosthetic heart valve of FIG. 2, a portion of the lower outer surface 204 is covered by a fabric skirt 206 and the valve support 208 with associated prosthetic leaflets attached thereto (not shown) is disposed within the interior I defined by the stent frame 201. The exemplary prosthetic mitral valve thus provides a one-way flow from the upper region 210 to the lower region 212, with the leaflets performing the valving function as the skilled artisan will recognize. Thus, an expanded and exemplary prosthetic mitral valve will occupy the left atrium, with a lower surface 214 residing on an upper annular surface within the left atrium, wherein the valve support provides a flow path through the leaflets and into and through the annulus leading to the left ventricle.

In this exemplary and illustrated case, the wire and loop connection forming the connected wire pair P is made at a lower or distal end, within the lower region 212, of the prosthetic heart valve, operatively engaging and connecting to a junction J between two struts 202 as shown. Because the fabric skirt 206 covers the subject struts 202 and junction J formed therebetween, the non-looped wire W and/or looped wire L may penetrate the fabric to reach and connect with the subject strut. Further, as shown, the wire and loop connection described above is made preferably at a junction J of two struts 202, wrapping around the junction J to prevent both unwanted sliding of the connection along the struts 202 which may result in unwanted tearing of the fabric skirt 206. As discussed above, two or more, or a plurality, of non-looped and looped wire pairs P may also be connected in the same or similar manner and in spaced-apart relation to a first non-looped and looped wire pair P. Since the non-looped and looped wire pair(s) P are operatively connected to strut junction(s) D at a distal or lower end of the prosthetic mitral valve device as shown, in a transseptal delivery to the left atrium, the upper region 210 of the stent 201 will exit the lumen 104 of the delivery catheter 102 into the left atrium first, before the distal or lower end or region 212 of the stent. The connected wire pairs P may be used to turn and position the expanded stent 201 so that the lower surface 214 is at least partially engaged with an upper annular surface within the left atrium.

It is to be understood that the non-looped and looped pair(s) P are connected before collapsing the prosthetic heart valve stent frame 201 into the proximal end and lumen 104 of the delivery catheter 102 for translational delivery therealong to the subject heart chamber where expansion of the prosthetic heart valve frame occurs when it is released from the distal end of the lumen 104 of the delivery catheter 102. Thus the non-looped and looped wire pair(s) P may extend through the lumen 104 of the delivery catheter 102 and comprise a length that allows a distal end to reach the subject heart chamber while allowing an operator to manipulate the proximal ends of the non-looped wires W and looped wires L connected in wire pair(s) P. Further, in some embodiments, more than one non-looped positioning wire W may be combined with a looped wire W. In other embodiments, more than one looped wire L may be combined with one non-looped wire W.